



NFPA
The Food Safety People

**NATIONAL
 FOOD**

**PROCESSORS
 ASSOCIATION**

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 Lloyd R. Hontz

Supplemental Comments
[Docket No. 97-013P] Performance Standards for the
Production of Processed Meat and Poultry Products;
66 Federal Register 12590; February 27, 2001

John R. Cady
*President and
 Chief Executive Officer*

Dear Ms. Riley:

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The National Food Processors Association (NFPA) is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

In comments submitted on September 10, 2001, NFPA objected strenuously to the FSIS proposal to eliminate the established and proven effective canning regulations in favor of performance standards for canned products. These proposed standards have the potential to reduce the level of public health protection provided by the current regulatory requirements for thermally processed, commercially sterile meat and poultry products. The canning regulations promulgated by FDA more than 25 years ago and more recently adopted by FSIS upon our petition have represented an outstanding example of an industry/agency cooperative effort designed to successfully address a recognized food safety problem. They have also been incorporated at the international level into the "Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods CAC/RCP 23-1979, Rev 2 (1993)" by the Codex Alimentarius Commission.

WASHINGTON, DC
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Performance Standards for Thermally Processed, Commercially Sterile Products

NFPA vigorously objected to the Agency proposal to replace the existing comprehensive canning regulations with abbreviated performance standards for thermally processed, commercially sterile foods and urged the Agency to withdraw this portion of its February 27 proposal. Our objections to the overall thrust of this portion of the FSIS proposal were numerous. Some of the key elements of our prior comments are listed below. We maintain our position on these points.

- FSIS cited no public health basis for the proposed change.
- It would likely require significant economic expenditures for validation of thermal processes that are already exceedingly conservative and whose adequacy has been validated by many, many years of production of safe products.
- The primary justification for the proposed change is to make the requirements for this industry segment consistent with those for other meat and poultry products, but this overlooked the fact that the change would create great disharmony with requirements of the FDA canning regulations (21 CFR 113) and with the recommended code of practice of the Codex Alimentarius Commission.
- Another stated justification for the proposed change is to provide greater flexibility for industry to produce safe product in the most efficient manner. However, over the past 15 years many changes have been made, both at the request of industry and on the Agency's own volition, to eliminate unnecessary requirements. While a few additional changes along this line could be made, these can be accomplished easily with minor amendment of the existing regulations.
- We determined that the Agency's proposed version of guidelines for industry merely converted all required "shalls" to recommended "shoulds." We believe that years of experience have shown that the mix of mandatory practices and advisory recommendations in the existing canning regulations are on target and need not be changed.
- We strongly objected to the elimination of the regulatory recognition of the process authority.
- We disagreed with FSIS setting a specific performance standard for minimum health purposes.
- We found unclear the extent of processes intended to be covered by this proposal.
- Finally, we urged the Agency to withdraw from its proposed rule the proposed § 9 CFR 430.5 dealing with thermally processed, commercially sterile products. We added that at a later date and under a separate docket, the Agency could undertake refinement of the existing regulations, while retaining their essential provisions.

These supplemental comments address the refinements that we believe are appropriate at this time.

FSIS could significantly reduce the number of pages of regulations and eliminate any confusion for processors of both meat and poultry products and inspection personnel over minor wording differences between the two current sets of regulations by combining and recodifying the currently separate requirements for meat and poultry into a single section of the *Code of Federal Regulations*.

In addition, certain minor refinements to the combined regulations could probably be made without reproposing the rule.

NFPA has prepared a short list of existing sections of the regulation, which should be amended for one of three reasons: to eliminate requirements not involving food safety; to eliminate lingering unnecessary prior approvals; or to consolidate redundant requirements. They are addressed individually below (Citations are listed as 3** to reference both the meat and the poultry requirements found in 9 *CFR* 318 and 381):

Non-safety requirements

3.301 Containers and closures**

We recommend either rescinding in its entirety paragraph (a) *Examination and cleaning of empty containers*, or changing the “shalls” therein to “shoulds.” While examination and cleaning of empty containers has been and will continue to be common industry practice, it is not critical to the delivery of the thermal process and it is only tenuously relevant to container integrity.

For similar reasons, we recommend rescinding section (1) under paragraph (f) *Handling of containers after closure*. Again, it is prudent industry practice to take precautions to minimize the potential for damage to can seams or seals after closure. However, history has shown that although spoilage can occur, foodborne illness very rarely results from container leakage. Thus, minimizing container damage and container leakage remains a quality issue, not a public health issue.

3.305 Equipment and procedures for heat processing systems**

We believe that paragraph (g) *Equipment maintenance* of this section could also be rescinded or changed to a recommendation rather than a requirement. All the items covered under this section on equipment maintenance are matters that firms should address. However, the most appropriate mechanism to deal with this is through a prerequisite program or other industry practice that provides a foundation upon which a successful thermal processing operation can be built. Maintenance of equipment, while important, is not generally directly related to food safety.

3.309 Finished product inspection**

We recommend rescinding all of section (d) on procedures for finished product inspection, including all of (d)(1) on *Incubation of shelf stable canned product* and (d)(2) on *Container condition*. NFPA worked diligently with FSIS over many years on modification to the prescriptive requirement for incubation of canned products. Incubation is a form of end-product testing that is ineffective as a routine means for assuring the safety of canned food products. Though there may be occasions when a firm might desire to incubate samples of new products to verify process adequacy, there is no need for this to be a regulatory requirement. In a February 17, 1999 memo from Paul Thompson, Director of the FSIS Technical Service Center, the Agency acknowledged that prescriptive incubation requirements are not required if an establishment can otherwise attest to the safety and stability of its finished products, e.g., the firm's "process schedule adequately provides for safety and stability."

Likewise the provisions on container condition are relics of the former FSIS inspection philosophy that relied on inspection personnel, rather than the establishment to assure that only normal appearing containers are shipped or that abnormal containers are handled properly. In fact, the establishment is responsible for the safety of containers placed into commerce and these regulatory provisions are not needed for assuring Agency enforcement authority if an establishment fails to meet its responsibilities in this regard.

Lingering Prior Approval Requirements

In a series of amendments to the FSIS canning regulations, including one on elimination of prior approval requirements for Partial Quality Control (PQC) programs, the Agency previously has eliminated the vast majority of its prior approval requirements for canning establishments. However, to date a number of prior approval requirements previously have been overlooked. NFPA believes that the following requirements should be rescinded for reasons consistent with the Agency's earlier actions.

3.301 Containers and closures**

Section (f)(2) on *handling of containers after closure* addresses the amount of time permitted between closing or sealing containers and the initiation of thermal processing; the 2-hour limit requirement is a conservative rule of thumb for an acceptable period that will not result in insipient spoilage of the product prior to beginning the thermal process. However, the Agency recognized that on a case-by-case basis, longer periods of time between closing and processing may not present a problem. Unfortunately, the regulation requires the permission of the Administrator before a firm can exceed the 2-hour limit. In order to place responsibility on the

firm where it belongs, this section could be amended to make the 2-1 our limit a recommendation rather than a requirement by changing the “shall” to a “should.” Alternatively, the offending sentence could be reworded as follows: “A longer period of time between closing and the initiation of thermal processing is permissible based on appropriate data or the recommendation of a thermal processing authority.”

3.304 Operations in the thermal processing area**

The prior approval requirement for alternative methods for measurement of pH should be rescinded. We suggest the paragraph be amended as follows:

~~Unless other methods are approved by the Administrator,~~ Potentiometric methods using electronic instruments (pH meters), or other methods of suitable accuracy for the intended purpose, shall be used for making pH determinations when a maximum pH value is specified as a critical factor in a process schedule.

3.305 Equipment and procedures for heat processing systems**

Paragraph (h) should be amended as follows to reflect the fact that the Agency no longer approves chemicals used in meat and poultry plants:

Cooling canal water shall be chlorinated or treated with a chemical ~~approved by the Administrator~~ as having a bactericidal effect equivalent to chlorination.

3.308 Finished product inspection**

Paragraph (d)(1)(iv) should be rescinded to eliminate the need for Agency prior approval of process deviation handling before a firm may release product.

3.309 Finished product inspection**

Prior approval requirements for container condition under section (l)(2) are remedied by our prior suggestion to eliminate this section as a requirement not directly related to safety.

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Redundancies

3.305 Equipment and procedures for heat processing systems** **(b) *Pressure processing in steam***

Four different types of thermal processing systems are covered under 9 CFR 3**.305(b). They are (1) *Batch still retorts*, (2) *Batch agitating retorts*, (3) *Continuous rotary retorts*, and (4) *Hydrostatic retorts*. A number of requirements are common to two or more of these systems. For example, sections (i), (ii), and (iii) are identical (except for one word) for batch still, batch agitating and continuous rotary retorts. Also the section on *Bleeders and vent mufflers* is identical for all four systems, as is a portion of the section on *Bleeders*.

If carefully crafted so as not to introduce confusion, these sections could be combined in one paragraph to cover all appropriate sections without redundancy.

Other Refinements

At this time, we do not believe that further changes, such as we informally shared with the Agency a number of years ago, are required to permit the FSIS canning regulations to continue to serve as an exemplary example of science-based regulations that have made a valuable contribution to food safety.

Certainly any other changes that the Agency might consider making should be the subject of a new regulatory proposal upon which the public, including the food canning industry, would have a full opportunity to comment.

Respectfully submitted,



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National Food Processors Association